

## **MDxHealth Reports New ConfirmMDx Risk Score Data at 11th World Congress on Urological Research**

***Results demonstrate that patients can be stratified for low and high grade prostate cancer***

**IRVINE, CA, and HERSTAL, BELGIUM, September 10, 2015** – MDxHealth SA (Euronext: MDXH), today announced data demonstrating that a newly developed algorithm, based on ConfirmMDx test scores (ConfirmMDx Risk Score), stratifies men with DNA methylation positive prostate biopsies for risk of low and high-grade prostate cancer (PCa). The data will be presented at the 11th World Congress on Urological Research in Nijmegen, The Netherlands, 9-11 September 2015 (<http://esur-sbur.uroweb.org>).

Using a training cohort of biopsy samples from 803 patients, MDxHealth has developed an algorithm based on the ConfirmMDx test that estimates the risk of harboring high-grade PCa for patients with histologically negative biopsies. The results are expressed in a risk score, combining both the methylation intensity and traditional clinical characteristics like Prostate Specific Antigen (PSA), age, pathology and DRE.

The ConfirmMDx Risk Score was further validated in a separate cohort of 102 men that underwent a 12-core biopsy (20 men with no cancer, 46 with Gleason score (GS) 6 and 36 with GS $\geq$ 7 prostate cancer). The ConfirmMDx Risk Score was able to differentiate men with aggressive, high-grade PCa from those men with indolent disease.

The current gold standard in assessing a patient's risk of harboring aggressive PCa or indolent prostate cancer are the Gleason scoring system and the National Comprehensive Cancer Network (NCCN). However, due to the limitations of a standard biopsy procedure the risk of high-grade cancer is underestimated in up to 30% of men.

Dr. Philip J. Ginsburg, Chief Medical Officer of MDxHealth, commented: "In previous studies, when compared with current clinical parameters, we have shown that ConfirmMDx testing of negative biopsy cases is the most significant independent predictor of harboring prostate cancer. In addition, our test has a negative predictive value of 96% for the detection of high-grade cancer.

"Application of the ConfirmMDx Risk Score to the population men with a previous negative biopsy but considered at risk for undetected cancer, will improve patient stratification, helping to identify the men at highest risk for aggressive prostate cancer meriting repeat biopsy and treatment. Additionally, these data demonstrate that test's ability to distinguish between men with aggressive, high-grade PCa from those men with indolent disease, suggest that there could be a role for ConfirmMDx in guiding treatment decision making for men considering active surveillance."

**[About ConfirmMDx<sup>®</sup> for Prostate Cancer](#)**

Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25-35% of those men receive false-negative results. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of undetected cancer, leading to a high rate of repeat biopsies, even on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx for Prostate Cancer is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This "halo" around a cancer lesion can be present despite cells having a normal appearance under the microscope. Thus ConfirmMDx for Prostate Cancer aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure. Performance of the proprietary ConfirmMDx genes and technology has been published in 45 studies on over 5,000 patients tested. The ConfirmMDx test has qualified for Medicare reimbursement as of November 3, 2014 and is also available to more than 152 million insured lives via private health insurance plans.

### **About MDxHealth**

MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit [mdxhealth.com](http://mdxhealth.com) and follow us on Twitter at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth).

### **For more information:**

Dr. Jan Groen, CEO  
MDxHealth  
US: +1 949 812 6979  
BE: +32 4 364 20 70  
[info@mdxhealth.com](mailto:info@mdxhealth.com)

Mike Sinclair (PR)  
Halsin Partners  
UK: +44 20 7318 2955  
Cell: +44 7968 022075  
[msinclair@halsin.com](mailto:msinclair@halsin.com)

Amber Fennell (IR)  
Consillium Strategic  
Communications  
UK: +44 20 3709 5701  
Cell: + 44 7739658783  
[fennell@consilium-comms.com](mailto:fennell@consilium-comms.com)

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